

EPA Reg. No. 66222-267



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 9, 2018

Lauren Seabrook
Federal Regulatory Manager
Makhteshim-Agan of North America, Inc
3120 Highwoods Blvd, Suite 100
Raleigh, NC 27604

Subject: PRIA CSF Amendment – Adding an unregistered source of active ingredient.
Product Name: 2,4-D ACID FLAKE
EPA Registration Number: 66222-267
Application Date: May 12, 2017
Decision Number: 529472

Dear Ms. Seabrook:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

The data requirements for corrosion characteristics (Guidelines 830.6320) are not satisfied. A one-year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Please note that the record for this product currently contains the following CSFs:

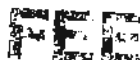
- Basic CSF dated 05/09/2017
- Alternate CSF I dated 05/09/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Grant Rowland by phone at 703-347-0254, or via email at rowland.grant@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Kathryn V. Montague".

Kathryn Montague, Product Manager 23
Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D440660; FILE SYMBOL No.: 66222-267; PRODUCT NAME: 2, 4-D Acid Flake;
DECISION No.: 529472; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: Yes

DATE: December 5, 2017

SUBJECT: Product Chemistry Review of "2, 4-D Acid Flake"

FROM: Shyam Mathur, Ph. D
Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)/RD (7505P)

Shyam Mathur

12-5-17
AJ Sheth
12/5/2017

TO: Grant Rowland / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

REGISTRANT: MANA Incorporation.
MRID Numbers: 50249701 & 50349707

INTRODUCTION:

MANA Inc. has submitted an application to amend the registration of the "2, 4-D Acid Flake" technical product. Currently the subject product is 100% repack of registered pesticide product with [REDACTED] as represented by the basic CSF dated July 8, 2016. The amendment involved the submission of a new proposed basic CSF dated May 9, 2017 (unregistered source) and the current 100% repack CSF moves to a new alternate CSF #1 dated May 9, 2017. The new proposed basic CSF is supported by group A & group B product chemistry data with the MRID Nos. 50249701 to -07.

Proposed new Basic CSF (dated 05-09-2017): Production site - [REDACTED]

Proposed Alternate CSF #1 (dated 05-09-2017) [100% re-pack of [REDACTED]]

CITAB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

1. Group A guidelines:

830.1550 (product identity & composition)

The submitted data are acceptable. Active ingredient and process-related impurities were adequately described (MRID No. 50249701). The nominal concentration of the active ingredient 2, 4-D acid Flake in the proposed basic CSF (98.4%) is the average derived from the 5 batch preliminary analysis, and is within the certified limits of the product label claim nominal concentration of 97%. The submitted data satisfy the data requirements for 40CFR §158.320.

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830.1600 (description of materials used to produce the product)

The product chemistry data submitted for the guideline 830.1600 (description of starting materials) are acceptable. The registrant has submitted MSDS's for all the starting materials used for the production of 2, 4-D Acid Flake technical at the new production site under MRID No. 50249701. The information presented meets the data requirements for 40CFR§158.325.

830.1620 (description of production process)

The product chemistry data submitted data for the guideline 830.1620 (description of production process) are acceptable. The technical is produced in [REDACTED]. The registrant has provided description of the production process, flow charts, chemical reactions pathways, and quality control measures were provided in MRID No. 50249701. The information presented meets the data requirement for 40CFR§158.330.

830.1670 (discussion on the formation of impurities)

The product chemistry data submitted for the guideline 830.1670 (discussion on the formation of impurities) are acceptable. Detailed information regarding the origins of impurities was provided (MRID 50249701). Potential impurities were identified and quantified as part of the five-batch analysis. The registrant has reported [REDACTED] on the proposed basic CSF. The discussions have been provided on their formation. The registrant has analyzed the technical acid for impurities of toxicological concern like chlorinated dioxins (PCDD's) & dibenzofuran (PCDF's). The results of this study show that all detected levels of Halogenated Dibenzo-p-dioxin or Dibenzofuran contaminants in 2,4-D Acid were well below commonly accepted limits (< 0.1 ppb). The information presented satisfy the data requirements for 40CFR§158.340.

830.1700 (preliminary analysis)

The submitted data are acceptable as given under MRID No. 50249702. The average of the 5 batches for AI was 98.4%. This result is within the currently approved nominal concentration of 97.0%. In order to keep the current source of active ingredient, the nominal concentration is proposed at 97.0%. The content of the active ingredient was determined by external standard calibration using validated HPLC-UV method using reverse phase column with detector operating at 284 nm. Confidence in the method of analysis is established through validation tests, which examine the results for linearity, selectivity, recovery, repeatability, intermediate precision, limit of quantification and limit of detection. The structure of the active ingredient was confirmed by IR, UV, ¹NMR and MS methods. The significant impurities were [REDACTED]

The Impurities were [REDACTED]

DP BARCODE No.: D440660; **FILE SYMBOL No.:** 66222-267; **PRODUCT NAME:** 2, 4-D Acid Flake;
DECISION No.: 529472; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** Yes

[REDACTED]

[REDACTED]. The analysis of five lots of 2,4-D Technical Flake indicated that the dioxin furan compounds none exceeded the thresh-hold levels indicated in 40 CFR Chapter I Part 766.27. The data submitted satisfy the data requirements of 40CFR§158.345[MRID Nos. 50249702].

830.1750 (certified limits)

The product chemistry data submitted for the guideline 830.1750 satisfy the data requirements of 40CFR§158.350. The registrant has proposed standard certified limits for the AI whereas the proposed certified limits for the impurities are based on the five batch analysis. The proposed certified limits are in compliance with 40CFR§158.350 [MRID No. 50249701].

830.1800 (enforcement analytical method)

The active ingredient 2, 4-D acid was determined by HPLC-UV method with UV detector operating at 284 nm and quantification was done by external standard technique. The method was validated for selectivity, linearity, and recovery. The information presented meets the data requirements for 40 CFR §158.355 [MRID No. 50249701].

2. Group B guidelines (physical-chemical properties): Data submitted under MRID Nos. 50249703 to 50249707 satisfy the data requirements of 40CFR§158.310.

CONCLUSIONS:

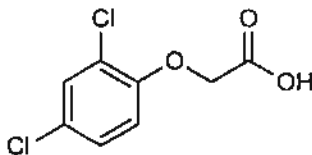
The CITAB has reviewed the proposed basic CSF and the supporting group A product chemistry data for "2, 4-D Acid Flake" and has concluded that:

1. The product chemistry data submitted for guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.
2. The proposed basic CSF (dated 05-09-2017) and proposed alt CSF #1 (dated 05-09-2017; 100% re-pack of [REDACTED]) are acceptable and is supported by five batch analysis.
3. The analysis of five lots of 2, 4-D Acid Flake indicated that the contents of PCDD/F's compounds did not exceed the thresh-hold levels indicated in 40CFR Chapter I Part 766.27 in the technical 2, 4-D Acid Flake.

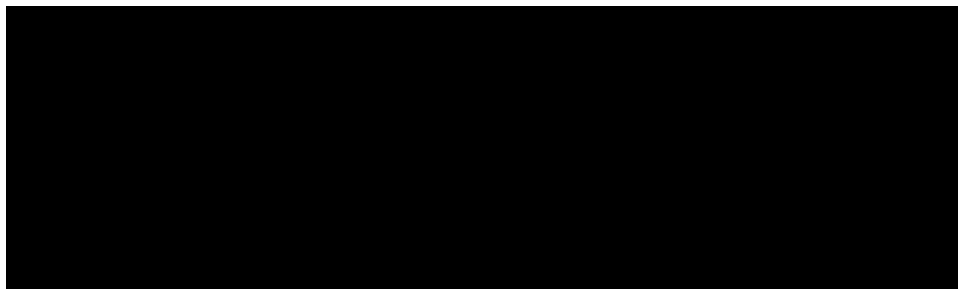
DP BARCODE No.: D440660; FILE SYMBOL No.: 66222-267; PRODUCT NAME: 2, 4-D Acid Flake;
DECISION No.: 529472; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: Yes

830.1550. Product identity & composition: (MRID No. 50249701)

IUPAC Name: (2,4-dichlorophenoxy)acetic acid
C.A. Name: 2-(2,4-dichlorophenoxy)acetic acid
CAS Registry Number: 94-75-7
Molecular Formula: $C_8H_6Cl_2O_3$
Molecular Weight: 221.04
Structure:



Manufacturing facility:



DP BARCODE No.: D44066, FILE SYMBOL No.: 66222-267; PRODUCT NAME: 2, 4-D Acid Flake;
 DECISION No.: 529472; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: Yes

Table 1. Manufacturing and Impurity Data for "2, 4 D Acid Flake"				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	50249701	A	See summary of findings
830.1600	Description of materials used to produce the product	50249701	A	See summary of findings
830.1620	Description of production process	50249701	A	See summary of findings
830.1670	Discussion of formation of impurities	50249701	A	See summary of findings
830.1700	Preliminary analysis	50249702	A	See summary of findings
830.1750	Certified limits	50249701	A	See summary of findings
830.1800	Enforcement analytical method	50249701 50249702	A	See summary of findings
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

DP BARCODE No.: D44066; **FILE SYMBOL No.:** 66222-267; **PRODUCT NAME:** 2, 4-D Acid Flake;
DECISION No.: 529472; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** Yes

830.1800 (enforcement analytical method)
(MRID No. 50249701)

The active ingredient 2, 4-D Acid Flake was determined by using the validated analytical method with a reverse phase HPLC/UV and external standard calibration technique. The method was validated for linearity, accuracy & precision. The validation results are provided in the following table:

Parameters	Acceptable conditions	Results
Specificity	acceptable	
Linearity	$R^2 > 0.99$	$R^2 = 0.999$
Instrument precision	$RSD \leq 1\%$	$RSD = 0.18\%$
Precision of the method (repeatability)	$RSD \leq 1.3\%$	$RSD = 0.10\%$

Apparatus & Equipment

Shimadzu liquid chromatograph

Detector UV

Thermostat CTO-10AS

HPLC column: Hypersil BDS C18, 150 mm x 4.6 mm (5µm grains)

Chromatographic conditions

The column temperature: 35°C

The mobile phase: water – 80% acetic acid, 55 + 4 (V+V) → (B)
100 % methanol → (A)

Gradient profile:	time [min]	B [%]
	0.01	60
	15.0	60
	30.0	20
	37.2	60
	45.0	60

- Flow rate: $v = 1.0$ ml/min
- Wavelength: $\lambda = 284$ nm
- The volume of sample injected: 20 µl

Under conditions as above the retention time of 2,4-D technical was 12.2 ± 0.2 min.

DP BARCODE No.: D44066, FILE SYMBOL No.: 66222-267; PRODUCT NAME: 2, 4-D Acid Flake;
 DECISION No.: 529472; PC Code(s): 030001; ACTION CODE: R351; FOOD Use: Yes

Table 2: Physical and Chemical Properties for "2, 4-D Acid Flake"				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	50249704	A	White
830.6303	Physical state	50249704	A	Solid @ 25°C
830.6304	Odor	50249704	A	Characteristics odor
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions	50249707	A	TS was found to be stable at RT & at 54°C when placed in contact with metallic Fe & Al and corresponding ions for 14 days. No change in appearance and loss of the Al was observed.
830.6314	Oxidation/reduction: chemical incompatibility	50249704	A	TS was found to be compatible with Zn powder and incompatible with oxidizing agents and alkalinity.
830.6315	Flammability	50249704	A	Non-flammable
830.6316	Explosibility	50249704	A	TS does not present any explosive properties
830.6317	Accelerated storage stability	50249706	A	TS was found to be stable for 2 weeks at 54°C
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics		N	No data submitted or cited
830.7000	pH	50249705	A	2.86 at 22.5°C (1% w/v aqueous suspension)
830.7050	UV/Visible absorption		G	No data submitted or cited
830.7100	Viscosity		NA	This product is a solid
830.7200	Melting point	50249706	A	138.2°C
830.7220	Boiling point		NA	This product is a solid with no lower m.p.
830.7300	Density (cited)	50249703	A	1.508 g/cc @20°C (Reference: C. D. S. Tomlin (Ed.), "The Pesticide Manual", 13th Edition, p. 255, BCPC Publications, Hampshire, 2003).
830.7370	Dissociation constants in water (DC)	50249705	A	pK _a = 3.6 (titration with 0.01 M NaOH) @20°C
830.7550	Partition coefficient (cited)	50249703	A	Log P _{ow} = 2.58-2.83 (pH 1) & = 0.04-0.33 (pH 5) (Reference: C. D. S. Tomlin (Ed.), "The Pesticide Manual", 13th Edition, p. 255, BCPC Publications, Hampshire, 2003).
830.7840	Water solubility (cited)	50249703	A	311 mg/l (pH 11), 20.031 mg/l (pH 5), 23.18 mg/l (pH 7) & 34.196 mg/l (pH 9) @25°C (Reference: C. D. S. Tomlin (Ed.), "The Pesticide Manual", 255, BCPC Publications, Hampshire, 2003). Solubility for organic solvents refer to table below
830.7950	Vapor pressure (cited)	50249703	A	1.86 x 10 ⁻² Pa @25°C (Reference: C. D. S. Tomlin (Ed.), "The Pesticide Manual", 13th Edition, p. 255, BCPC Publications, Hampshire, 2003).

DP BARCODE No.: D44066; **FILE SYMBOL No.:** 66222-267; **PRODUCT NAME:** 2, 4-D Acid Flake;
DECISION No.: 529472; **PC Code(s):** 030001; **ACTION CODE:** R351; **FOOD Use:** Yes

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress;
U = Up-grade (additional information required); W = waivers

Solubility in organic solvents [MRID No. 50249703]

[Reference: C. D. S. Tomlin (Ed.), "The Pesticide Manual", 13th Edition, p. 255, BCPC Publications, Hampshire, 2003)].

Solvents	Solubility in g/l at 25°C
Diethyl ether	243
Heptane	1.1
Toluene	120
Ethanol	1250



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 16, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-529472
EPA File Symbol or Registration Number: 66222-267
Product Name: 2,4-D Acid Flake
EPA Receipt Date: 12-May-2017
EPA Company Number: 66222
Company Name: MAKHTESHIM AGAN OF NORTH AMERICA, INC.

LAUREN SEABROOK
MAKHTESHIM AGAN OF NORTH AMERICA, INC.
D/B/A ADAMA
3120 HIGHWOODS BLVD., SUITE 100
RALEIGH, NC 27604-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0510.

Sincerely,

A handwritten signature in black ink, appearing to be "J. L. L.", is written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division



REGISTRATION ACTION:
PRIA Amendment

FEE CATEGORY: R351
REGISTRATION FEE: \$13,226

May 12, 2017

VIA ONLINE SUBMISSION PORTAL

Mrs. Kathryn Montague, PM Team 23 (7505P)
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: 2,4-D Acid Flake EPA Reg. No.66222-267

PRIA Amendment (R351) – Adding a new unregistered source of active ingredient

Dear Mrs. Montague,

Makhteshim Agan of North America, Inc. (d/b/a ADAMA) is submitting an application to amend the registration of 2,4-D acid flake to add an unregistered source of active ingredient. The proposed 2,4-D acid flake Basic CSF should be added to the file upon acceptance. The current CSF on file, dated 7-8-2016, should now become the Alt#1 CSF on file, since it is 100% re-pack formulation.

In support of this regulatory action, this submission includes:

1. EPA Form 8570-1; Application for Pesticide Registration
2. EPA Form 8570-4; Proposed, 2,4-D acid flake Basic CSF (dated 5-9-2017)
3. EPA Form 8570-4; Proposed, 2,4-D acid flake Alt#1 CSF (dated 5-9-2017)
4. EPA Form 8570-4; Approved, 2,4-D acid flake Basic CSF (dated 7-8-2016)
5. EPA Form 8570-34; Certification with Respect to Citation of Data
6. EPA Form 8570-35; Data Matrix; Agency Internal Use Copy (CBI)
7. EPA Form 8570-35; Data Matrix; Public File Copy
8. Transmittal Document
9. Copy of PRIA payment
10. MRID 50249701; 2,4-D Acid Flake Product Identity and Composition
11. MRID 50249702; 2,4-D Acid Flake 5 Batch Analysis
12. MRID 50249703; 2,4-D Acid Flake Physical and Chemical Properties Waiver Requests
13. MRID 50249704; Physicochemical Properties of 2,4-D Technical
14. MRID 50249705; Determination of Physical and Chemical Properties of 2,4-D Technical
15. MRID 50249706; 2,4-D Acid 980 TC Physicochemical Properties
16. MRID 50249707; 2,4-D Acid 980 TC Physicochemical Properties Part II

ADAMA

ADAMA | 3120 Highwoods Blvd. Suite 100 Raleigh, NC 27604
Telephone +1 919 256 9300 | Facsimile +1 919 256 9308 | www.adama.com



Should you have any questions or comments pertaining to this submission, please feel free to contact me via email at lauren.seabrook@adama.com or via phone at (919) 256-9357.

Sincerely,

A handwritten signature in black ink, appearing to read "Lauren Seabrook", is positioned above the printed name.

Lauren Seabrook
Federal Regulatory Manager

ADAMA

ADAMA | 3120 Highwoods Blvd. Suite 100 Raleigh, NC 27604
Telephone +1 919 256 9300 | Facsimile +1 919 256 9308 | www.adama.com



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number MANA (d/b/a ADAMA) / 66222-267	2. EPA Product Manager Kay Montague	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) MANA (d/b/a ADAMA) / 2,4-D Acid Flake	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Makhteshim-Agan of North America, Inc. (d/b/a ADAMA) 3120 Highwoods Blvd, Suite 100 Raleigh, NC 27604 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R351 (57: Amendment adding an unregistered source of active ingredient).
The PRIA fee of \$13,226 has been paid.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 500 kg		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Lauren Seabrook		Title Federal Regulatory Manager		Telephone No. (Include Area Code) (919) 256-9357	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature Lauren Seabrook		3. Title Federal Regulatory Manager			
4. Typed Name Lauren Seabrook		5. Date 5/12/2017			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s)	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date	Typed or Printed Name and Title
--	------	---------------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 4, 2017	EPA Reg. No./ File Symbol: 66222-267	Page 1 of 7
Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: 2,4-D Acid Flake
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	50249701	Makhteshim Agan of North America	OWN	
830.1600	Description of Materials Used to Produce the Product	50249701	Makhteshim Agan of North America	OWN	
830.1620	Description of Production Process	50249701	Makhteshim Agan of North America	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	50249701	Makhteshim Agan of North America	OWN	
830.1700	Preliminary Analysis	50249702	Makhteshim Agan of North America	OWN	
830.1750	Certified Limits	50249701	Makhteshim Agan of North America	OWN	
830.1800	Enforcement Analytical Method	50249702	Makhteshim Agan of North America	OWN	
		50249701	Makhteshim Agan of North America	OWN	
830.6302	Color	50249704	Makhteshim Agan of North America	OWN	
830.6303	Physical State	50249704	Makhteshim Agan of North America	OWN	
830.6304	Odor	50249704	Makhteshim Agan of North America	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	50249707	Makhteshim Agan of North America	OWN	
		50249706	Makhteshim Agan of North America	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	50249704	Makhteshim Agan of North America	OWN	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: May 4, 2017	EPA Reg. No./ File Symbol: 66222-267	Page 2 of 7
Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product: 2,4-D Acid Flake	
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability	50249704	Makhteshim Agan of North America	OWN	
830.6316	Explosibility	50249704	Makhteshim Agan of North America	OWN	
830.6317	Storage Stability	50249703	Makhteshim Agan of North America	OWN	PRN 92-5 ²
830.6319	Miscibility				Not Required ³
830.6320	Corrosion Characteristics	50249703	Makhteshim Agan of North America	OWN	PRN 92-5 ²
830.6321	Dielectric Breakdown Voltage				Not required ³
830.7000	pH	50249705	Makhteshim Agan of North America	OWN	
830.7050	UV/Visible Absorption	50249702	Makhteshim Agan of North America	OWN	
830.7100	Viscosity				Not required ³
830.7200	Melting Point/Melting Range	50249706	Makhteshim Agan of North America	OWN	
830.7220	Boiling Point/Boiling Range				Not required ³
830.7300	Density/Relative Density/Bulk Density	50249703	Makhteshim Agan of North America	OWN/PL	
830.7370	Dissociation Constants in Water	50249705	Makhteshim Agan of North America	OWN	
830.7520	Particle Size, Fiber Length, and Diameter Distribution	50249703	Makhteshim Agan of North America	OWN	Waiver ³
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	50249703	Makhteshim Agan of North America	OWN/PL	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604		Product: 2,4-D Acid Flake
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	50249703	Makhteshim Agan of North America	OWN/PL	
830.7860	Water Solubility, Generator Column Method				
830.7950	Vapor Pressure	50249703	Makhteshim Agan of North America	OWN/PL	
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
Product Specific and Generic Data Requirements					

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product: 2,4-D Acid Flake	
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Makhteshim Agan of North America, Inc. is using the cite-all option to satisfy generic data requirements and will make offers-to-pay to the following companies on the 2,4-D data submitters list of April 6, 2017					
		Cite-All	Nufarm Americas, Inc.	PAY	
		Cite-All	Bayer Cropscience LP	PAY	
		Cite-All	FMC Corporation	PAY	
		Cite-All	E.I. DuPont de Nemours and Company	PAY	
		Cite-All	The Dow Chemical Co.	PAY	
		Cite-All	The Scotts Company	PAY	
		Cite-All	Balcom Chemicals, Inc.	PAY	
		Cite-All	Lebanon Seaboard Corporation	PAY	
		Cite-All	Winfield Solutions, LLC	PAY	
		Cite-All	PBI/Gordon Corp	PAY	
		Cite-All	Dubois Chemicals, Inc.	PAY	
		Cite-All	Amvac Chemical Corporation	PAY	
		Cite-All	Helena Chemical Company	PAY	
		Cite-All	BASF Corporation	PAY	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product: 2,4-D Acid Flake	
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Chemsico	PAY	
		Cite-All	ADAMA Agan Ltd.	OWN	
		Cite-All	ADAMA Makhteshim Ltd.	OWN	
		Cite-All	Drexel Chemical Company	PAY	
		Cite-All	PBI/Gordon Corp	PAY	
		Cite-All	Loveland Products, Inc.	PAY	
		Cite-All	Nufarm Limited	PAY	
		Cite-All	Inter-Chem, Ltd.	PAY	
		Cite-All	Albaugh, LLC	PAY	
		Cite-All	Atanor S.A.	PAY	
		Cite-All	Marman USA Inc	PAY	
		Cite-All	2,4-D Task Force	PAY	
		Cite-All	GB Biosciences, LLC	PAY	
		Cite-All	Sandoz Agro Inc	PAY	
		Cite-All	Nufarm USA, Inc.	PAY	
		Cite-All	Agro-Gor Corp	PAY	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Industry Task Force II on 2,4-D Research	PAY	
		Cite-All	Dow Agrosiences LLC	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	Gharda USA, Inc	PAY	
		Cite-All	Nufarm, Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Bayer Advanced	PAY	
		Cite-All	Growell Limited	PAY	
		Cite-All	FIFRA Endangered Species Task Force	OWN	See endnote ⁴
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agvalue-Clopyr, LLC	PAY	
		Cite-All	Agricultural Handler Exposure Task Force	PAY	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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DATA MATRIX

Date: May 4, 2017	EPA Reg. No./ File Symbol: 66222-267	Page 7 of 7
Applicant's/Registrant's Name and Address: Makhteshim Agan of North America, Inc. d/b/a/ ADAMA 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604	Product: 2,4-D Acid Flake	
Ingredient: 2,4-D (CAS No. 94-75-7)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	2,4-DP-P Task Force	PAY	
		Cite-All	Tacoma Ag, LLC	PAY	
		Cite-All	Generic Endangered Species Task Force	OWN	See endnote ⁴
		Cite-All	Genmerica NA LLC	PAY	

Signature 	Name and Title Lauren Seabrook, Federal Regulatory Manager	Date May 4, 2017
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Endnotes for Data Matrix for 2,4-D Acid Flake

¹ **830.1650** - These data are not required for the registration of a technical grade active ingredient product. See 830.1620 for production process information.

² **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data can be submitted after registration if EPA requires this study. Makhteshim Agan of North America, Inc. (MANA) will submit the data as a condition of registration.

³ **830.6319, 830.6321, 830.7100, 830.7220, 830.7520** – 2,4-D Acid Flake is a solid technical material and is not an emulsifiable concentrate to be diluted with petroleum solvents. Therefore, miscibility data are not required for this technical. 2,4-D Acid Flake is not an end use product to be used around electrical equipment, therefore data for dielectric breakdown constant are not required. 2,4-D Acid Flake is a solid and not a liquid, therefore, viscosity data are not required for this product. Boiling point data are not required for solid products. MANA is seeking a waiver for particle size, fiber length and diameter distribution because 2,4-D acid is not water insoluble and is not a fibrous material.

⁴ Makhteshim Agan of North America, Inc. is a member in good standing with this task force.

TRANSMITTAL DOCUMENT

2,4-D Acid Flake: PRIA Amendment (R351) – Adding a new unregistered source of active ingredient

Submitter:

Makhteshim Agan of North America, Inc. (d/b/a ADAMA)
 3120 Highwoods Blvd, Suite 100
 Raleigh, NC 27604

Regulatory action/reason for submission:

PRIA Amendment (R351) – Adding a new unregistered source of active ingredient

Transmittal date:

May 12, 2017

List of submitted studies:

MRID No.	Volume No.	Guidelines	Study Title
50249701	1 of 1	OPPTS 830.1550, 830.1600, 830.1620, 830.1670	2,4-D Acid Flake - Product Identity and Composition, Description of Materials Used to Produce the Product, Description of the Production Process, and Discussion of Formation of Impurities
50249702	1 of 1	OPPTS 830.1700, 830.1750, 830.1800	2,4-D Acid Flake – Preliminary Analysis, Certified Limits, and Enforcement Analytical Methods
50249703	1 of 1	OPPTS 830.6317, 830.6321, 830.7300, 830.7520, 830.7550, 830.7840, 830.7860, 830.7950	2,4-D Acid Flake - Physical and Chemical Properties Waiver Requests
50249704	1 of 1	OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316	Physicochemical Properties of 2,4-D Technical
50249705	1 of 1	OPPTS 830.7000, 830.7370	Determination of Physical and Chemical Properties of 2,4-D Technical
50249706	1 of 1	OPPTS 830.6313, 830.7200	2,4-D Acid 980 TC Physicochemical Properties
50249707	1 of 1	OPPTS 830.6313	2,4-D Acid 980 TC Physicochemical Properties Part II

Company official:


Lauren Seabrook
 Federal Regulatory Manager
 D +919-256-9357 | F +919-256-9309
 E lauren.seabrook@us.adama.com

From: [Karina Castro](#)
To: [Lauren Seabrook](#)
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Friday, May 5, 2017 4:35:05 PM

Lauren,

See below. They passed this on to me.

Thanks,

Karina Castro
Federal Regulatory Manager
D 1 919-256-9322 | M 1 928-580-6949
E karina.castro@adama.com
ADAMA
www.adama.com

-----Original Message-----

From: notification@pay.gov [<mailto:notification@pay.gov>]
Sent: Friday, May 5, 2017 4:34 PM
To: Karina Castro <karina.castro@adama.com>
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. To confirm that the payment processed as expected, you may refer to your bank statement on the scheduled payment date. If you have any questions or wish to cancel this payment, you will need to contact the agency you paid at your earliest convenience.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 2629N0QL
Agency Tracking ID: 75239232502

Account Holder Name: Makhteshim Agan of North America
Transaction Type: ACH Debit
Transaction Amount: \$13,226.00
Payment Date: 05/08/2017
Account Type: Business Checking
Routing Number: 121000248
Account Number: *****4242

Transaction Date: 05/05/2017 04:33:35 PM EDT
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number: 66222-267
Company Name: Makhteshim-Agan of North
Company Number: 66222
Action Code: R-351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

PROCESSING REQUEST

Reg # 66222-ENT(-267) Decision # 519681

Description: 100% REPACK NEW PRODUCT

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 11/30/16

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 07/08/2016 BASIC

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

MANY THANK YOUs! ☺

Reviewer: Theresa (Terri) Stowe

Division: Registration Division (7505P)

Phone: (703) 305-6117

Date: 12 / 08 / 2016



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

66222-267

Date of Issuance:

11/30/2016

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

2,4-D Acid Flake

Name and Address of Registrant (include ZIP Code):

Makhteshim Agan of North America, Inc. (d/b/a ADAMA)
3120 Highwoods Blvd., Suite 100
Raleigh, NC 27604

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 66222-267."
3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Signature of Approving Official:

Kathryn V. Montague, Product Manager 23
Herbicides Branch, Registration Division (7505P)
Office of Pesticide Programs

Date:

11/30/2016

4. You are required to comply with the data requirements described in the DCI Order and/or Registration Review Workplans identified below:

- a. 2,4-D GDCI-030001-1330

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/l?p=chemicalsearch:l>

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/08/2016.

If you have any questions, please contact Terri Stowe at (703) 305-6117 or by email at stowe.terri@epa.gov.

Enclosure

2,4-D Acid Flake

HERBICIDE

For Manufacturing Use Only

ACCEPTED

11/30/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. **66222-267**

ACTIVE INGREDIENT:

2,4-dichlorophenoxyacetic acid.....97.0%

OTHER INGREDIENTS:.....3.0%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER / PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Manufactured for:

Makhteshim Agan of North America, Inc. d/b/a ADAMA

3120 Highwoods Blvd., Suite 100

Raleigh, NC 27604

How can we help? 1-866-406-6262

EPA Reg. No. 66222-xxx

EPA Est. No. XXXXXXXXXX

NET CONTENTS: _____

FIRST AID

IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

For emergency medical treatment information, call Prosar 24 hours a day at 1-877-250-9291.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive • Causes Irreversible Eye Damage • Harmful If Swallowed, Inhaled, or Absorbed Through the Skin

Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. When handling this product, wear eye protection (face shield, or chemical goggles), and chemical resistant gloves. Remove and wash contaminated clothing and clean protective equipment before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Manufacturing Use Only

Manufacturing Chemical: Do not ship or store with food, feed, drugs, or clothing.

Only for formulation into an herbicide for the following uses: **Crops:** corn (field corn, popcorn and sweet corn), sorghum (grain sorghum (milo) and forage sorghum), small grains (wheat, oats, barley, millet and rye), rice, soybeans (preplant), strawberries, sugarcane, grass pastures, rangeland, fallow cropland and crop stubble, areas in the conservation reserve program, grass seed crops, orchard floors (apple, pear, fruit, citrus, and nut), asparagus, blueberries, cranberries, grapes (only in California), hops, potatoes (fresh market only); **and Non-Crop:** ornamental trees, shrubs and vines, turf (including lawns, golf courses, cemeteries, parks, airfields), roadsides, noncropland areas including rights-of-way, railroads, drainage ditch banks, fence rows, tree injection treatments, forest site preparation, forest conifer release, Christmas trees, woody plant control in non-cropland areas and aquatic weed control.

Wettable powder formulations must be packaged in water-soluble packages.

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE:

Keep container tightly closed when not in use. This product can be stored in an unheated building.

PESTICIDE DISPOSAL:

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the hazardous waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

NONREFILLABLE RIGID CONTAINERS - 50lb OR LESS

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. DO NOT cut or weld metal containers.

Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse** as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. **Pressure rinse** as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

NONREFILLABLE NONRIGID CONTAINERS

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into equipment. Offer for recycling if available or dispose of bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. For minor spills, follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

REFILLABLE RIGID CONTAINERS - LARGER THAN 5 gal/50 lb

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

NONREFILLABLE RIGID CONTAINERS - LARGER THAN 5 gal/50 lb

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. DO NOT cut or weld metal containers.

Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse** as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse** as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

LIMITATION OF WARRANTY AND LIABILITY

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES and LIMITATIONS OF LIABILITY**.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of ADAMA. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, ADAMA makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of ADAMA is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, ADAMA disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at ADAMA's election, the replacement of product.

Optional Text for Import Labels: [Shipped for further Labeling and Packaging. NOT INTENDED FOR USE BY CONSUMER]



2,4-D Acid Flake (66222-xxx)

(EPA app 07-19-16, EPA acceptance xx-xx-xx)

Product ingredient source information may be entitled to confidential treatment

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060. Approval expires 05-31-98

		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other		OPP Identifier Number	
Application for Pesticide - Section I							
1. Company/Product Number EPA Reg. No. 66222-xxx EAT			2. EPA Product Manager Kathryn Montague		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted		
4. Company/Product (Name) 2,4-D Acid Flake			PM# Team 23				
5. Name and Address of Applicant (Include ZIP Code) Makhteshim Agan of North America, Inc. (d/b/a ADAMA) 3120 Highwoods Blvd., Suite 100 Raleigh, North Carolina 27604 <input type="checkbox"/> Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____				
Section - II							
<input type="checkbox"/> Amendment - Explain below.				<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____				<input type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.				<input checked="" type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) PRIA 300 Makhteshim Agan of North America, Inc. (d/b/a ADAMA) is submitting an application for a new 2,4-D Acid Flake product. This product is 100% repack of the [REDACTED]							
Section - III							
1. Material This Product Will Be Packaged In:							
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____				
Section - IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)							
Name Lauren Seabrook			Title Federal Regulatory Manager			Telephone No. (Include Area Code) 919-256-9357	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.						6. Date Application Received (Stamped)	
2. Signature 			3. Title Federal Regulatory Manager				
4. Typed Name Lauren Seabrook			5. Date July 19, 2016				

DOCUMENTUM



REGISTRATION ACTION:

PRIA Amendment

FEE CATEGORY: R300

REGISTRATION FEE: \$1,582

July 14, 2016

VIA ONLINE SUBMISSION PORTAL

Mrs. Kathryn Montague, PM Team 23 (7505P)
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: 2,4-D Acid Flake; EPA Reg. No. 66222-xxx EAT
PRIA Amendment (R300) – Registration of a new technical product (100% repack)

Dear Mrs. Montague,

Makhteshim Agan of North America, Inc. (d/b/a ADAMA) is submitting an application for a new 2,4-D Acid Flake product. This product is 100% repack of [REDACTED]
[REDACTED]

In support of this regulatory action, this submission includes:

1. EPA Form 8570-1 ; Application for Pesticide Registration
2. EPA Form 8570-4 ; Proposed, Basic CSF (dated 7-8-2016)
3. EPA Form 8570- 27; Formulators Exemption
4. 2,4-D Acid Flake Master Label
5. Copy of PRIA payment

Should you have any questions or comments pertaining to this submission, please feel free to contact me via email at lauren.seabrook@adama.com or via phone at (919) 256-9357.

Sincerely,

Lauren Seabrook
Federal Regulatory Manager

ADAMA

ADAMA | 3120 Highwoods Blvd. Suite 100 Raleigh, NC 27604
Telephone +1 919 256 9300 | Facsimile +1 919 256 9308 | www.adama.com

DOCUMENT 44



United States
Environmental Protection Agency
 Washington, DC 20460
Formulator's Exemption Statement
 (40 CFR 152.85)

Applicant's Name and Address Makhteshim Agan of North America, Inc. (d/b/a ADAMA) 3120 Highwoods Blvd., Suite 100 Raleigh, North Carolina 27604	EPA File Symbol/Registration Number 66222-xxx EAT
	Product Name 2,4-D Acid Flake
	Date of Confidential Statement of Formula (EPA Form 8570-4) 07/08/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

2,4-Dichlorophenoxyacetic Acid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
2,4-Dichlorophenoxyacetic Acid		
Signature 	Name and Title Lauren Seabrook - Federal	Date 07/08/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

23

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 7/19/16

Experts In-Processing Signature: NA Date 7/27/16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>66222-EAT</u>		EPA Receipt Date: <u>7/19/16</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) <u>no inerts to review - 100% Re-Pack</u>	yes <input type="checkbox"/>	no <input type="checkbox"/>		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X
	Certificate and data matrix consistent				
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes <input type="checkbox"/>	no <input type="checkbox"/>		
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)		X		
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X
	a) Selective Method (Fee category experts use)	yes <input type="checkbox"/>	no <input type="checkbox"/>		
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>		
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>		
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)		X		
7	Is the data package consistent with PR Notice 86-5				X
8	Notice of Filing included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* Documentation: (Pass / Fail)

- Signature missing on Formulator's Exemption Statement
- Contacted the submission on 7-27-16
- Licenses the revised form on 7-27-16
- Request forms are complete

* Zments: (Pass / Fail)

- No zments to review
- (no y) Re-Pack

* PRN 11-3: (Pass / Fail)

- No studies submitted

DN 7-28-16

* Overall Status: (Pass / Fail)

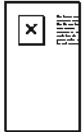
Kang, Ji Yeon

From: Lauren Seabrook <Lauren.Seabrook@adama.com>
Sent: Wednesday, July 27, 2016 2:54 PM
To: Kang, Ji Yeon
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: 2,4-D Acid Flake (EPA Reg. No. 66222-EAT)
Attachments: removed.txt; 2016-07-08 2,4-D Acid Flake (66222-xxx) - EPA 8570-27 Formulators Exemption - updated 7.27.16 LLS.pdf

Hi Ms. Kang,

The updated Formulator's Exemption Statement (EPA Form 8570-27) is attached.

Thanks,
Lauren



Lauren Seabrook
Federal Regulatory Manager
D +919-256-9357 | M +919-633-2094
E lauren.seabrook@adama.com

ADAMA
www.adama.com

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Wednesday, July 27, 2016 1:39 PM
To: Lauren Seabrook <Lauren.Seabrook@adama.com>
Cc: Ashe, Anthony <Ashe.Anthony@epa.gov>
Subject: Submission to EPA: 2,4-D Acid Flake (EPA Reg. No. 66222-EAT)

Dear Ms. Seabrook,

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product 2,4-D Acid Flake (EPA Reg. No. 66222-EAT). We have found few deficiencies with the submissions that will need to be addressed:

1. Signature is missing on the Formulator's Exemption Statement (EPA Form 8570-27)

Please send the necessary document before Aug 10th so that we may further process your submission. After Aug 10th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Joyce Kang

Contractor, US EPA
2777 S. Crystal Drive, S-4823
Arlington, VA 22202
(703) 347-0416
Email: kang.joyce@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 26, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-519681
EPA File Symbol or Registration Number: 66222-EAT
Product Name: 2,4-D Acid Flake
EPA Receipt Date: 19-Jul-2016
EPA Company Number: 66222
Company Name: MAKHTESHIM AGAN OF NORTH AMERICA, INC.

LAUREN SEABROOK
MAKHTESHIM AGAN OF NORTH AMERICA, INC.
D/B/A ADAMA
3120 HIGHWOODS BLVD., SUITE 100
RALEIGH, NC 27604-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. ...".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9892420~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S-

989242

EPA File Symbol/Reg. No.

66222-EAT

Pin-Punch Date:

7/19/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: \$ 1582

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Joseph Marenese Date: 7/20/16

Remarks:

added in
DOCUMENTATION



PRISM Documentum

You are here: [EPA Home](#) » [PRISM Documentum](#) » [Inbox](#)

Info **Comments** **Progress**



ISB In Processing : 66222-EAT 5989242 2016-07-19

Description: 66222-EAT 5989242 2016-07-19

From: Doc Admin

Received: 7/20/2016 9:35 AM

WorkFlow Instructions:

cd_12854_989242 : Comments

<u>Comment</u>	<u>Author</u>	<u>Date</u> ▲
REQUESTED ACTION CODE = R300 GRANTED ACTION CO DE = R300 Amount due = 1582 Parent action = Child action = Other Remarks = IR-4 related submission (Y or N)? n Similarity Clinic Review Required (Y/N)? n	Marchese, Jacquelyn I.	7/20/2016 9:35 AM

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• [Document Types Guide](#)

From: notification@pay.gov
To: [Lauren Seabrook](#)
Subject: Pay.gov Payment Confirmation: PRIA Service Fees
Date: Wednesday, July 13, 2016 4:35:17 PM

Your payment has been submitted to Pay.gov and the details are below. To confirm that the payment processed as expected, you may refer to your bank statement on the scheduled payment date. If you have any questions or wish to cancel this payment, you will need to contact the agency you paid at your earliest convenience.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25SNNPMK
Agency Tracking ID: 75052736433

Account Holder Name: Makhteshim Agan of North America
Transaction Type: ACH Debit
Transaction Amount: \$1,582.00
Payment Date: 07/14/2016
Account Type: Business Checking
Routing Number: 121000248
Account Number: *****4242

Transaction Date: 07/13/2016 04:34:41 PM EDT
Total Payments Scheduled: 1
Frequency: OneTime

Registration Number:
Company Name: Makhteshim Agan of North
Company Number: 66222
Action Code: R300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

